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ART UNIT	PAPER NUMBER
1803	23

DATE MAILED: 07/27/95

Below is a communication from the EXAMINER in charge of this application
COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

- ☐ is extended to run _____ from the date of the Final Rejection
- ☒ continues to run two from the date of the Final Rejection
- ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date that the shortened statutory period for response expires as set forth above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 6/16/95, has been considered with the following affect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
- ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
 - ☐ They raise new issues that would require further consideration and/or search. (See Note).
 - ☐ They raise the issue of new matter. (See Note).
 - ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
 - ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing of an appeal, the proposed amendment ☒ will be ☐ will not be, entered and the status of the claims in this application would be as follows:

Allowed claims: _____

Claims objected to: _____

Claims rejected: 2-4, 47 + 50-67 See attachment.

However:

- ☐ The rejection of claims _____ on references is deemed to be overcome by applicant's response.
 - ☒ The rejection of claims 47, 60, 63-67 on non-reference grounds only is deemed to be overcome by applicant's response.
4. ☐ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection.
5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☒ Other See attachment

See Interview Summary of 6/30/95

5 Attachment to PTOL-303

Note: Applicants have not addressed the objection to the specification under 35 U.S.C. § 132, regarding new matter at page 150 of the specification.

10 Re rejection under the judicially created doctrine of obviousness type double patenting, the examiner has met his burden to establish a *prima facie* case of obviousness. Note Applicants do not contend that the DNA, genes and the like, as claimed were not known in the art but merely their insertion into maize was not motivated nor suggested by the teaching in '045. The instant specification does not teach the "novel" claimed phenotype, Applicants admit that the "DNA" was previously well known, thus the person having ordinary skill in the art would expect the "DNA" to act in its known and expected way in the absence of evidence to the contrary and thus its use be considered obviousness.

15 Re use of "consisting" of vs. "comprising" language a current copy of MPEP § 706.03(y) is attached. Bolding has been added by the examiner to emphasize what is proper language in Markush-type claims. Note that the section referred to by applicants has nothing to do with the use of "comprising" in a claim. Clearly the scope of comprising and consisting of is not the same.

706.03(y) Improper Markush Group

20 Ex parte Markush , 1925 C.D. 126; 340 O.G. 839, sanctions, in chemical cases, claiming a genus expressed as a group **consisting of certain specified materials**. This type of claim is employed when there is no commonly accepted generic expression which is commensurate in scope with the field which the applicant desires to cover.

25 Inventions in metallurgy, refractories, ceramics, pharmacy, pharmacology, and biology are most frequently claimed under the Markush formula but purely mechanical features or process steps may also be claimed by using the Markush style of claiming, see , 214 USPQ 551 (Bd. Appl's 1981); In re Gaubert , 187 USPQ 664 (CCPA 1975) and , 206 USPQ 300 (CCPA 1980). **It is improper to use the term "comprising" instead of consisting of .** Ex parte Dotter , 12 USPQ 382. Regarding the normally prohibited

30 inclusion of Markush claims of varying scope in the same case, see , 1934 C.D. 5; 441 O.G. 509.

35 The use of Markush claims of diminishing scope should not, in itself, be considered a sufficient basis for objection to or rejection of claims. However, if such a practice renders the claims indefinite or if it results in undue multiplicity, an appropriate rejection should be made. This practice with respect to Markush claims of diminishing scope is being continued.

40 The materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or

45 from the prior art that all of them possess this property. While in the past the test for Markush-type claims was applied as liberally as possible, present practice which holds that claims reciting Markush groups are not generic claims (MPEP @ 803)

50 may subject the groups to a more stringent test for propriety of the recited members. Where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression.

55 When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if "wherein R is a material selected from the group consisting of A, B, C and D" is a proper limitation, then "wherein R is A, B, C or D" shall also be considered proper.

SUBGENUS CLAIM

60 A situation may occur in which a patentee has presented a number of examples which, in the examiner's opinion, are sufficiently representative to support a generic claim and yet a court may subsequently hold the claim invalid on the ground of undue breadth. Where this happens the patentee is often limited to species claims which may not provide him with suitable protection.

65 The allowance of a Markush-type claim under a true genus claim would appear to be beneficial to the applicant without imposing any undue burden on the Patent and Trademark Office or in any way detracting from the rights of the public. Such a subgenus claim would enable the applicant to claim all the disclosed operative embodiments and afford applicant an intermediate level of protection in the event the true genus claims should be subsequently held invalid.

70 The examiners are therefore instructed not to reject a Markush-type claim merely because of the presence of a true genus claim embrace thereof.

See also MPEP @ 608.01(p) and @ 715.03.

See MPEP @ 803 for restriction practice re Markush-type claims.

Serial No. 08/113,561
Art Unit 1803

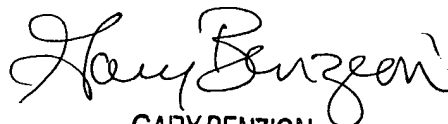
4 of 4

75 Re rejection of claims 2-4 and 47-67 under 35 U.S.C. § 103 as obvious over 07/508,045, Applicants argue that the examiner had not addressed arguments to "the manner in which the invention was made" and cite *In re Bell*. Note that the rejection was not based on ~~the~~ such logic and thus it was deemed a moot point. The '045 case teaches transgenic corn and teaches that known and enabled genes, such as *Bt*, can be placed into maize to function in their known and expected way. Thus previously known and isolated genes, which have been shown to function transgenically, once inserted into maize, by any process, are made obvious by '045 in the absence of a reason to question either the product formed, i.e., does it function in its known and expected way, or its enablement based on the facts of art placed before
80 person having skill in the art. Arguments to operability (enablement?) and obviousness are arguments that are separately addressed under 35 U.S.C. § 112 and 103. Since the references cited in the specification teach the DNA to have been isolated and expressed, their specific use is enabled. Whether or not they would have an effect on the phenotype, as claimed, is a separate issue of enablement or one of the scope of enablement. In terms of motivation, genes such as *Bt*, which are known insecticidal toxins, have
85 been expressed in other crops to kill insects, and are seen in the art to function precisely in this manner, need no more motivation than that to teach or suggest their use. Applicants are correct that a gene which has no known function in a plant and which has not been demonstrated in the art to affect a plants phenotype, such as insect resistance or increase in storage proteins, would not provide -- by its mere existence -- motivation to place it in a plant, however, in the absence of actually placing such a gene in a
90 plant there would be no clear reasonable expectation of success in producing a transgenic maize plant that render it identifiable over a corresponding untransformed plant.

Re Goldman et al. arguments as applied above have been considered, rejection is maintained.

95 Any inquiry concerning this or earlier communication from the examiner should be directed to Gary Benzion, Ph.D whose telephone number is (703) 308-1119. The examiner can normally be reached on Monday-Friday from 8 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas W. Robinson can be reached on (703)-308-2897. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703)-308-4227. Informal
100 communication may be sent via facsimile at 703-305-7362. The examiner should be notified at extension X-1119 of any informal communication prior to its transmittal.

Benzion
07/26/95


GARY BENZION
PRIMARY EXAMINER
GROUP 1800